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## DRUG POLICY

# Proton Pump Inhibitors

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Proton Pump Inhibitors (PPIs) Quantity Limit criteria is to encourage appropriate prescribing quantities as recommended by FDA-approved product labeling. The intent of the proton pump inhibitors (PPIs) step therapy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The criteria will encourage the use of the more cost-effective generic PPIs prior to the use of a brand or more costly generic when clinically appropriate while maintaining optimal therapeutic outcomes.

AcipHex (rabeprazole), Dexilant (dexlansoprazole), Esomeprazole Strontium, Nexium (esomeprazole), Prevacid (lansoprazole), Prilosec (omeprazole), and Protonix (pantoprazole) are all PPIs that suppress gastric acid secretion by specific inhibition of the H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system at the secretory surface of the gastric parietal cell. They reduce gastric acidity by acting specifically on the proton pump which is the final step in acid production.

### POLICY

- I. Prior authorization for Omeprazole 10mg & 40mg (generic Prilosec), Lansoprazole (generic Prevacid), or Pantoprazole (generic Protonix) is not required for quantities less than or equal to 2 dosage units per day. Additional quantities may be considered **medically necessary** if the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.
- II. Prior authorization for Omeprazole 20 mg (generic Prilosec) is not required for quantities less than or equal to 4 dosage units per day. Additional quantities may be considered **medically necessary**

if the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

III. Brand and generic AcipHex, Dexilant, Esomeprazole strontium, and brand or generic Nexium may be considered **medically necessary** if the following criteria is met:

- Patient must have tried and failed a therapeutic trial of at least **two** preferred PPIs (Prilosec (omeprazole), Prevacid (lansoprazole), and/or Protonix (pantoprazole)).
- The requested amount does not exceed 2 dosage units per day for AcipHex, Esomeprazole strontium, and Nexium or 1 dosage unit per day for Dexilant unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

**Approval will be 12 months**

IV. Brand and generic AcipHex Sprinkles may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules unless Step Therapy Exception Criteria for Approval is met .
- The requested amount does not exceed 1 dosage unit per day unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

**Approval will be 12 months**

V. Prilosec packets, Protonix Packets, and Nexium Packets may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have a contraindication to or tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules.
- The requested amount does not exceed 2 dosage units per day unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

**Approval will be 12 months**

VI. Brand and generic Prevacid Solutabs may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have a contraindication to or tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules; **OR** is unable to swallow capsules related to a medical condition or due to a nasogastric or gastrostomy tube.

- The requested amount does not exceed 2 dosage units per day unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

**Approval will be 12 months**

- VII. Medications included in this policy are considered **not medically necessary** for patients who do not meet the criteria set forth above.

**Quantity limits apply:**

<b>Drug Name</b>	<b>Standard Benefit Allowance</b>	<b>Post-Limit PA Quantity Limit (up to)</b>
Aciphex (rabeprazole)	60 tablets per 30 days	90 tablets per 30 days
Aciphex Sprinkles (rabeprazole)	30 capsules per 30 days	60 capsules per 30 days
Dexilant (dexlansoprazole)	30 capsules per 30 days	60 capsules per 30 days
Esomeprazole Strontium (esomeprazole strontium)	60 capsules per 30 days	90 capsules per 30 days
Nexium (esomeprazole)	60 capsules/packets per 30 days	90 capsules per 30 days
Prevacid (lansoprazole)	60 capsules/solutabs per 30 days	90 capsules/solutabs per 30 days
Prilosec (omeprazole)	60 capsules/packets per 30 days	90 capsules/packets per 30 days
Protonix (pantoprazole)	60 capsules/packets per 30 days	90 capsules/packets per 30 days

**PROCEDURES AND BILLING CODES**

***To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.***

- Code(s), if applicable

**REFERENCES**

- AcipHex [package insert]. Woodcliff Lake, NJ: Eisai, Inc.; November 2020.
- AcipHex Sprinkles [package insert]. Rockville, MD: Atyu Therapeutics, LLC/Cerecor, Inc.; November 2020.
- Dexilant [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
- Esomeprazole Strontium [package insert]. Glasgow, KY: Amneal Pharmaceuticals LLC; December 2020.
- Nexium [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2020.
- Omeprazole Capsules [package insert]. Weston, FL: Apotex Corp.; November 2020.
- Prevacid, Prevacid SoluTab [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
- Prilosec Granules [package insert]. Zug, Switzerland: Covis Pharma; November 2020.
- Protonix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; November 2020.
- Zegerid [package insert]. Bridgewater, NJ Salix Pharmaceuticals, Inc; November 2020.
- Shaheen N, Falk G, et al. ACG Clinical Guideline: Diagnosis and Management of Barrett's Esophagus. Am J Gastroenterol. 2016; 111:30-50.
- Katz P, Gerson L, et al. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. 2013; Vol 108:308-328.
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- Lanza FL, Chan F, Quigley E, et al. Guidelines for Prevention of NSAID-Related Ulcer Complications. Am J Gastroenterol 2009; 104: 728-738.
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## **POLICY HISTORY**

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